JTW

141-446

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT OPERATION

In re Application of:

Kositprapa et al.

Serial No.: **10/777,542** Group Art Unit: --

Filed: **February 12, 2004** Examiner: --

For: **NOVEL PHARMACEUTICAL FORMULATION CONTAINING A BIGUANIDE AND A THIAZOLIDINEDIONE DERIVATIVE**

New York, NY 10036
May 12, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

The following statement of relevance is submitted with the accompanying Form PTO/SB/08A.

Document Designation	Relevance
AA U.S.P. 3,174,901	Relates to a process for the oral treatment of diabetes.
AB U.S.P. 3,960,949	Relates to 1,2-biguanides.
AC U.S.P. 4,166,800	Relates to a process for preparation of microspheres.

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P.O. Box 1450
Alexamdria, VA 22313-1450
on May 12, 2004

Martin P. Endres, Reg. No. 35,498

Document Designation	Relevance
AD U.S.P. 4,389,330	Relates to a microencapsulation process.
AE U.S.P. 4,687,777	Relates to a thiazolidinedione derivative, useful as an antidiabetic agent.
AF U.S.P. 4,839,177	Relates to a system for the controlled-rate release of active substances.
AG U.S.P. 4,891,223	Relates to a controlled release delivery coating formulation for bioactive substances.
AH U.S.P. 4,968,507	Relates to a controlled porosity osmotic pump.
AI U.S.P. 5,294,770	Relates to a laser tablet treatment system.
AJ U.S.P. 5,356,913	Relates to the use of insulin sensitizing agents to treat hypertension.
AK U.S.P. 5,376,771	Relates to a high speed process for preparing orifices in pharmaceutical dosage forms.
AL U.S.P. 5,478,852	Relates to a use of thiazolidinedione derivatives and related antihyperglycemic agents in the treatment of impaired glucose tolerance in order to prevent or delay the onset of noninsulin-dependent diabetes mellitus.
AM U.S.P. 5,602,133	Relates to a use of thiazolidinedione derivatives and related antihyperglycemic agents in the treatment of disease states at risk for progressing to noninsulin-dependent diabetes mellitus.
AN U.S.P. 5,658,474	Relates to a method and apparatus for forming dispenser delivery ports.
AO U.S.P. 5,681,584	Relates to a controlled release drug delivery device.
AP U.S.P. 5,698,220	Relates to an asymmetric membrane for use in drug delivery devices.
AQ U.S.P. 5,719,188	Relates to the use of insulin sensitizing agents to treat hypertension.
AR U.S.P. 5,859,037	Relates to sulfonylurea-glitazone combinations for diabetes.

AS U.S.P. 5,916,584	Relates to a controlled release container with a core and an outer shell.
AT U.S.P. 5,952,356	Relates to a pharmaceutical composition containing an insulin sensitivity enhancer in combination with an antidiabetic agent.
AU U.S.P. 5,955,106	Relates to a pharmaceutical preparation containing metformin and a process for producing it.
AV U.S.P. 6,011,049	Relates to drug combinations for treating diabetes containing a glitazone, a biguanide and a sulfonylurea.
AW U.S.P. 6,031,004	Relates to salts of metformin.
AX U.S.P. 6,099,859	Relates to a controlled release oral tablet having a unitary core.
AY U.S.P. 6,153,632	Relates to a method and composition for the treatment of diabetes.
AZ U.S.P. 6,191,162	Relates to a method of reducing serum glucose levels.
BA U.S.P. 6,248,363	Relates to a solid carrier for improved delivery of active ingredients in pharmaceutical compositions.
BB U.S.P. 6,291,495	Relates to a method and composition for the treatment of diabetes.
BC U.S.P. 6,296,874	Relates to a core formulation comprising troglitazone and a biguanide.
BD U.S.P. 6,329,403	Relates to a pharmaceutical composition for the treatment of diabetes.
BE U.S.P. 6,383,471	Relates to a composition and method for improved delivery of ionizable hydrophobic therapeutic agents.
BF U.S.P. 6,403,121	Relates to a modulating formulation comprising pioglitazone and metformin.
BG U.S.P. 6,451,342	Relates to a formulation containing troglitazone and metformin.
BH U.S.P. 6,475,521	Relates to a biphasic controlled release delivery system for high solubility pharmaceuticals such as metformin.

BI U.S.P. 6,524,621	Relates to a formulation containing metformin and pioglitazone.
BJ U.S.P. 6,599,284	Relates to an osmotic device having a preformed passageway that increases in size.
BK US 2002/0071866	Relates to a dosage form having a barrier layer to laser ablation.
BL US 2003/0113371	Relates to a composition and method for maintaining blood glucose level by employing a hydrophilic matrix based oral controlled release antidiabetic composition.
BM US 2003/0118647	Relates to an extended release tablet of metformin.
BN US 2003/0118649	Relates to a drug delivery device.
CA WO 96/09823	Relates to a hypoglycemic agent from cryptolepis.
CB WO 98/11879	Relates to a gastric-retentive, oral drug dosage form for the controlled-release of sparingly soluble drugs and insoluble matter.
CC WO 98/55107	Relates to a gastric-retentive oral drug dosage form for controlled release of highly soluble drugs, including metformin.
CD WO 99/47128	Relates to a biphasic controlled release delivery system for high solubility pharmaceuticals, including metformin.
CE WO 99/55320	Relates to an oral formulation comprising a biguanide and an organic acid.
CF WO 00/28989	Relates to a pharmaceutical composition for modified release of an insulin sensitizer and another antidiabetic agent.
CG WO 00/72827	Relates to porous drug matrices and methods of manufacture thereof.
CH WO 01/35940	Relates to a composition comprising a thiazolidinedione, metformin hydrochloride and a pharmaceutically acceptable carrier.
CI WO 01/35941	Relates to a composition comprising a thiazolidinedione, metformin hydrochloride and a pharmaceutically acceptable carrier.

CJ WO 01/82875	Relates to a core formulation comprising pioglitazone and a biguanide.
CK WO 02/28181	Relates to a sustained release pharmaceutical composition containing metformin and a method for its production.
CL WO 03/004009	Relates to a pharmaceutical composition containing metformin.
CM WO 03/35029	Relates to a formulation of an erodible, gastric retentive oral dosage form using in vitro disintegration test data.
CN WO 03/047529	Relates to an extended release pharmaceutical tablet of metformin.
CO EP 0 169 105	Relates to a controlled porosity osmotic pump.
CP EP 0 283 369	Relates to a metformin dosage formulation.
CQ EP 0 381 181	Relates to a system for the controlled release of active agents and a process for its preparation.
CR EP 0 749 751	Relates to a pharmaceutical composition for use in treatment of diabetes.
CS EP 0 753 298	Relates to a synergistic combination comprising an insulin sensitizer and a HMG-CoA reductase inhibitor for treating arteriosclerosis.
CT EP 0 781 129	Relates to a pharmaceutical preparation containing metformin and a process for producing it.
DA P. Karttunen et al. International Journal of Clinical Pharmacology, Therapy and Toxicology, "The pharmacokinetics of metformin: a comparison of the properties of a rapid-release and a sustained-release preparation" Vol. 21 No. 1 – 1983, pp. 31-36.	Relates to a sustained release metformin dosage form.

DB — Relates to a sustained release metformin dosage form.
P.J. Pentikainen
International Journal of Clinical
Pharmacology, Therapy and Toxicology,
"Bioavailability of metformin. Comparison
of solution, rapidly dissolving tablet, and
three sustained release products"
Vol. 24 No. 4 – 1986, pp. 213-220

DC — Relates to a sustained release metformin dosage form.
Finnish Monograph of the Diformin®
Retard table with English translation

DD — Relates to metformin dosage form.
O.J. Lucis, MD, Ph. D., MSC
Canada Medical Association J.
Pharmacologic Update
"The status of metformin
in Canada" Vol. 128
January 1, 1983 pgs. 24-26

DE — Relates to pioglitazone.
G. Belcher and D.R. Matthews
Experiment and Clinical
Endocrinology & Diabetes
"Safety and tolerability
of pioglitazone" Suppl 2
(2000) pgs. 267-273

DF — Relates to a pioglitazone and metformin dosage forms.
Daniel Einhorn, MD et al.
Clinical Therapeutics
"Pioglitazone Hydrochloride in
Combination with Metformin in
the Treatment of Type 2 Diabetes
Mellitus: A Randomized, Placebo-
Controlled Study",
Vol. 22 No. 12, 2000 pgs. 1395-1413

DG — Relate to pioglitazone.
National Institute for Clinical Excellence
Technology Appraisal Guidance – No. 21
"Guidance on the Use of Pioglitazone for
Type 2 Diabetes Mellitus"
March 2001, pgs. 1-13

DH — Relates to pioglitazone.
The Pharmaceutical Journal
Vol. 265, No. 7122, p. 710
November 11, 2000 Clinical
(abstract only)

DI — Relates to a metformin extended-release tablet.
Product Labeling for
Glucophage® XR (July 2002)

DJ — Relates to combination therapy with pioglitazone and insulin in patients with Type 2 diabetes.
ADA Professional Section
Member Supplement
0474 and 0503-506 (Poster)
p. A110; A117

DK — Relates to an insulin-sensitizing diabetes agent.
Website www.findarticles.com
Clinician Reviews
"Insulin-Sensitizing Diabetes Agent"
September 1999

DL — Relates to pioglitazone dosage formulation.
ACTOS® product label
Physician's Desk Reference
55TH Edition, pp. 3171-3175

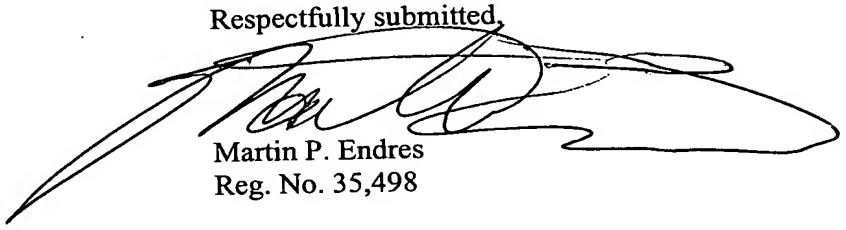
DM — Relates to Mediabet which is a tablet containing metformin.
Rote Liste No. 11081 the Medicament
MEDIABET of Medice; GLUCOBAY
of Bayer and GLUCOTARD of Boehringer
Mannheim, Chem.-Pharm. Fabrik Pütter
GmbH & Co. KG, Kuhloweg 37-39
Iserlohn/Germany, Editio Cantor Verlag
für Medizin und Naturwissenschaften GmbH, 1993.

DN — Relates to a metformin dosage formulation.
Abdallah et al.,
Preparation and Evaluation of
Metformin Hydrochloride
Controlled-Release Tablets STP
Pharma 4(1) pp. 15-20, 1988

In accordance with current Patent and Trademark Office practice no copy of the above listed United States Patents are filed herewith as well as copies of abstracts in English. Full text copies of all non-United States Patent prior art are enclosed herewith. It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein.

It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made or record therein. It is believed that no fee is required for submission of this Information Disclosure Statement under 37 C.F.R. §1.97(b). However, if a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 08-1540.

Respectfully submitted,



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PTO/SB/08A (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 5

Complete if Known	
Application Number	10/777,542
Filing Date	February 12, 2004
First Named Inventor	Unchalee Kositprapa
Art Unit	
Examiner Name	
Attorney Docket Number	141-446

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US-3,174,901	03-23-1965	Sterne	
	AB	US-3,960,949	06-01-1976	Ahrens et al.	
	AC	US-4,166,800	09-04-1979	Fong	
	AD	US-4,389,330	06-21-1983	Tice et al.	
	AE	US-4,687,777	08-18-1987	Meguro et al.	
	AF	US- 4,839,177	06-13-1989	Colombo et al.	
	AG	US- 4,891,223	01-02-1990	Ambegaonkar et al.	
	AH	US- 4,968,507	11-06-1990	Zentner et al.	
	AI	US- 5,294,770	03-15-1994	Riddle et al.	
	AJ	US- 5,356,913	10-18-1994	Colca	
	AK	US- 5,376,771	12-27-1994	Roy	
	AL	US-5,478,852	12-26-1995	Olefsky et al.	
	AM	US- 5,602,133	02-11-1997	Antonucci et al.	
	AN	US-5,658,474	08-19-1997	Geerke	
	AO	US-5,681,584	10-28-1997	Savastano et al.	
	AP	US- 5,698,220	12-16-1997	Cardinal et al.	
	AQ	US-5,719,188	02-17-1998	Colca	
	AR	US- 5,859,037	01-12-1999	Whitcomb	
	AS	US- 5,916,584	06-29-1999	O'Donoghue et al.	
	AT	US- 5,952,356	09-14-1999	Ikeda et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] -Number[4]- Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 5

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	AU	US- 5,955,106	09-21-1999	Moeckel et al.	
	AV	US-6,011,049	01-04-2000	Whitcomb	
	AW	US-6,031,004	02-29-2000	Timmins et al.	
	AX	US-6,099,859	08-08-2000	Cheng et al.	
	AY	US-6,153,632	11-28-2000	Rieveley	
	AZ	US- 6,191,162	02-20-2001	Byrd et al.	
	BA	US- 6,248,363	06-19-2001	Patel et al.	
	BB	US- 6,291,495	09-18-2001	Rieveley	
	BC	US- 6,296,874	10-02-2001	Cutie et al.	
	BD	US- 6,329,403	12-11-2001	Odaka et al.	
	BE	US- 6,383,471	05-07-2002	Chen et al.	
	BF	US-6,403,121	06-11-2002	Adjei et al.	
	BG	US- 6,451,342	09-17-2002	Adjei et al.	
	BH	US-6,475,521	11-05-2002	Timmins et al.	
	BI	US-6,524,621	02-25-2003	Adjei et al.	
	BJ	US- 6,599,284	07-29-2003	Faour	
	BK	US-2002/0071866	06-13-2002	Geerke	
	BL	US- 2003/0113371	06-19-2003	Dhawan et al.	
	BM	US- 2003/0118647	06-26-2003	Seth	
	BN	US- 20031011864	06-26-2003	Gao et al.	

FOREIGN PATENT DOCUMENTS

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	CA	WO 96/09823	04-04-1996	Luo et al.		
	CB	WO 98/11879	03-26-1998	Shell et al.		
	CC	WO 98/55107	12-10-1998	Shell et al.		
	CD	WO 99/47128	09-23-1999	Timmins et al.		
	CE	WO 99/55320	11-04-1999	Nishii et al.		
	CF	WO 00/28989	05-25-2000	Lewis et al.		
	CG	WO 00/72827	12-07-2000	Straub et al.		
	CH	WO 01/35940	05-25-2001	Lewis et al.		
	CI	WO 01/35941	05-25-2001	Lilliot et al.		
	CJ	WO 01/82875	11-08-2001	Cutie et al.		

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PTO/SB/08A (10-01)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 5

Complete if Known	
Application Number	10/777,542
Filing Date	February 12, 2004
First Named Inventor	Unchalee Kositprapa
Art Unit	
Examiner Name	
Attorney Docket Number	141-446

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		US-			
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	CK	WO 02/28181	04-11-2002	Gidwani et al.		
	CL	WO 03/004009	01-16-2003	Matharu et al.		
	CM	WO 03/035029	05-01-2003	Louie-Helm et al.		
	CN	WO 03/047529	06-12-2003	Seth et al.		
	CO	EP 0 169 105	01-22-1986	Zentner et al.		
	CP	EP 0 283 369	09-21-1988	Wiernsperger et al.		
	CQ	EP 0 381 181	08-08-1995	Wenzel et al.		
	CR	EP 0 749 751	12-27-1996	Ikeda et al.		
	CS	EP 0 753 298	11-21-2001	Tsujita et al.		
	CT	EP 0 781 129	07-02-1997	Moeckel et al.		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 5

Complete if Known	
Application Number	10/777,542
Filing Date	February 12, 2004
First Named Inventor	Unchalee Kositprapa
Group Art Unit	
Examiner Name	
Attorney Docket Number	141-446

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	DA	P. Karttunen et al., International Journal of Clinical Pharmacology, Therapy and Toxicology, "The pharmacokinetics of metformin: a comparison of the properties of a rapid release and a sustained-release preparation" Vol. 21, No. 1 - 1983, pp. 31-36.	
	DB	P.J. Pentikainen, International Journal of Clinical Pharmacology, Therapy and Toxicology, "Bioavailability of metformin. Comparison of solution, rapidly dissolving tablet, and three sustained-release products", Vol. 24, No. 4 - 1986, pp. 213-220.	
	DC	Finnish Monograph of the Diformin®, Retard tablet, with English translation	
	DD	O.J. Lucis, MD, Ph.D., MSC, Canada Medical Association J. Pharmacologic Update "The status of metformin in Canada" Vol. 128, January 1, 1983, pgs. 24-26.	
	DE	G. Belcher and D.R. Matthews, Experiment and Clinical Endrocrinology & Diabetes, "Safety and tolerability of pioglitazone" Suppl. 2 (2000) pgs. 267-273.	
	DF	Daniel Einhorn, MD et al., Clinical Therapeutics "Pioglitazone Hydrochloride in Combination with Metformin in the Treatment of Type 2 Diabetes Mellitus: A Randomized, Placebo-Controlled Study", Vol. 22, No. 12, 2000 pgs. 1395-1413.	
	DG	National Institute for Clinical Excellence Technology Appraisal Guidance - No. 21, "Guidance on the Use of Pioglitazone for Type 2 Diabetes Mellitus" March 2001, pgs. 1-13.	
	DH	The Pharmaceutical Journal, Vol. 265, No. 7122, p. 710 November 11, 2000 Clinical (abstract only).	

Examiner Signature		Date Considered	

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Sheet 5 of 5

Complete if Known	
Application Number	10/777,542
Filing Date	February 12, 2004
First Named Inventor	Unchalee Kositprapa
Group Art Unit	
Examiner Name	
Attorney Docket Number	141-446

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	DI	Product Labeling for Glucophage® XR (July 2002).	
	DJ	ADA Professional Section Member Supplement 0474 and 0503-506 (Poster) p. A110; A117	
	DK	Website www.findarticles.com, Clinician Reviews, "Insulin-Sensitizing Diabetes Agent" September 1999.	
	DL	ACTOS® product label, Physician's Desk Reference, 55th Edition, pp. 3171-3175	
	DM	Rote Liste No. 11081 the Medicament MEDIABET of Medice; GLUCOBAY of Bayer; and GLUCOTARD of Boehringer Mannheim, Chem.-Pharm. Fabrik Pütter GmbH & Co. KG, Kuhloweg 37-39 Iserlohn/Germany, Editio Cantor Verlag für Medizin und Naturwissenschaften GmbH, 1993.	
	DN	Abdallah et al., "Preparation and Evaluation of Metformin Hydrochloride Controlled-Release Tablets" STP Pharma 4(1) pp. 15-20, 1988.	

Examiner Signature		Date Considered	

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